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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,522	06/17/2008	Theresa M. Reineke	10738-97A	7556

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	PAPER NUMBER
1635	
MAIL DATE	DELIVERY MODE
02/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,522	REINEKE, THERESA M.	
	Examiner	Art Unit	
	Richard Schnizer	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-12,14,16-20 and 22-70* is/are pending in the application.

4a) Of the above claim(s) *1,3,6-8 and 30-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,14,16-20, 22-29, and 56-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/16/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 1/19/10.

Claims 56-70 were added.

Applicant's election without traverse of group 5 is acknowledged.

Claims 1, 3, 6-8, and 30-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/19/10.

Claims 9-12, 14, 16-20, and 22-29 are under consideration.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application Nos. 60/531,399 and 60/574,131, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '39 and '131 applications fail to provide support for most of the species of nucleic acid molecule set forth in instant claims 19 and 28, e.g. mRNA, tmRNA, tRNA, rRNA, siRNA, shRNA, PNA, artificial chromosomes, cDNA, PCR products, restriction fragments, and ribozymes. All claims under consideration embrace at least some of these species, and therefore do not have benefit of support from the priority documents. The effective filing date of the claims is therefore 12/20/04.

Compliance with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s). Applicant's attention is directed to the final rule making notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). **The specification, at page 113, paragraph 369, and at page 128, paragraph 421, discloses nucleotide sequences in excess of 9 bases that are not accompanied by a SEQ ID NO.** If these sequences are listed in the current Sequence Listing, then the specification should be amended to include the appropriate SEQ ID NO

in each of the passages referred to above. If these sequences are not in the current Sequence Listing, then in addition to amending the disclosure to include appropriate SEQ ID NOS, Applicant must also provide:

A substitute computer readable form (CRF) copy of the "Sequence Listing".

A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

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For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov.

Drawings

The application as filed contained no drawings.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 14, 16, 18, 19, 20, and 22-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Reineke et al (MOLECULAR THERAPY, (MAY 2004) Vol. 9, Supp. [1], pp. S139-S139. MA 362).

Reineke taught complexes comprising poly(hydroxylamidoamine)s and plasmid DNAs, and mammalian cells comprising the complexes. The plasmid was chemically modified to contain a reporter gene. Because mammalian cells are grown in culture, Reineke inherently taught pharmaceutical compositions and containers containing the complexes and the cells. See abstract. Thus Reineke anticipates the claims.

Claims 12, 14, 16, 18, 19, 20, and 22-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Liu et al (J. Am. Chem. Soc. 126: 7422-7423, 2004).

Liu taught complexes comprising poly(hydroxylamidoamine)s and plasmid DNAs, and mammalian cells comprising the complexes. The plasmid had been chemically modified to contain a luciferase reporter gene. Because mammalian cells are grown in culture, Liu inherently taught pharmaceutical compositions and containers containing the complexes and the cells. See entire document. Thus Liu anticipates the claims.

Claims 12, 22, 25, 26, 56, 57, 59, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by Akelah et al (Eur. Poly. J. 31(9): 903-909, 1995).

Akelah taught copolymers comprising polyamides and free hydroxyl groups formed by polycondensation of diethyl-L-tartrate with various diamines to form poly(L-tartaraamidoamines including poly(L-tartaradiethylenediamine and poly(L-tartaratriethylenediamine. Akelah also taught conjugation of an herbicide (2,4-D) to the poly(L-tartaraamidoamines. The herbicide was intended for delivery to cells. See abstract and schemes 1 and 2 on page 904, particularly where R = h or i in scheme 1. Thus Akelah anticipates claims 12, 56, 57, 59, and 70. Claims 22, 25, and 26 are included in the rejection because the conjugate of Akelah was formulated in an aqueous buffer solution and placed in a container (see page 907, right column, first full paragraph). Absent evidence to the contrary the aqueous buffer was a pharmaceutically acceptable excipient and the composition was a pharmaceutical composition.

Claims 9-12, 14, 16-20, and 22-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al (WO 01/87348).

A search of Medline and CAPLUS databases for the claim term "polyhydroxylamidoamine" revealed only 3 citations, all of which were authored by the instant inventor. Thus the term "polyhydroxylamidoamine" is not a widely recognized term of art. The instant specification does not provide a limiting definition for the term,

therefore it has been given it's broadest reasonable interpretation. This interpretation includes molecules that include several hydroxyl groups and at least one amidoamine group.

Baker taught polyamidoamine dendrimers modified with carbohydrate residues, such as mannose residues, for improving dendrimer binding to target cells (see abstract; page 42, lines 13-21; and page 44, line 26). Each carbohydrate is considered to be a polyhydroxyl group, so Baker taught polyhydroxyls conjugated to amidoamines, i.e. polyhydroxylamidoamines. Baker also taught that the dendrimers of the invention could be used to form complexes with agents to form pharmaceutical compositions delivery to cells, and specifically disclosed nucleic acid delivery, including antisense, oligonucleotide, and gene delivery. See e.g. page 3, lines 9-21; paragraph bridging pages 4 and 5, especially page 5 at lines 1-15; section IX at pages 53-54; page 56, lines 1-18; and section XII at pages 57-60. Oligonucleotides may be chemically modified by covalent attachment to the dendrimers (see e.g. example 5 at pages 64-68).

Baker envisions the treatment of in vitro and ex vivo in cultured and primary cells. Such cells must be grown in containers, so Baker inherently taught compositions and containers comprising cells comprising the complexes. See section VIII at page 50.

Baker also envisions kits comprising dendrimeric nanodevices that comprise a therapeutic agent (page 24, lines 18-24). and dendrimers PAGE 24, lines 18-24.

Baker also envisions complexes in which the active agent is a polypeptide. See page 28, lines 24-26; and page 36, lines 21-30.

Thus Baker anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 12, 22, 25, 56-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akelah et al (Eur. Poly. J. 31(9): 903-909, 1995).

Akelah taught copolymers of comprising polyamides and free hydroxyl groups formed by polycondensation of diethyl-L-tartrate with various diamines. Akelah also taught conjugation of an herbicide (2,4-D)tartrate derivatives. The herbicide is intended for delivery to cells. See abstract and schemes 1 and 2 on page 904. The conjugate of Akelah was formulated in an aqueous buffer solution and placed in a container (see page 907, right column, first full paragraph). Absent evidence to the contrary the aqueous buffer was a pharmaceutically acceptable excipient and the composition was a pharmaceutical composition. Thus Akelah anticipates and renders obvious claims 12, 22, 25, 26, 56, 57, 59, and 70.

Claim 9 is included in this rejection because it would have been obvious to one of ordinary skill in the art at the time of the invention to organize the elements of the invention of Akelah into a kit because one of skill in the art appreciates that organizing

experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

Claim 58 is included in this rejection because the diethyl-L- tartrate diester is structurally similar to the recited dimethyl-L-tartrate diester.

MPEP 2144.09 states that a prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." See also MPEP § 2144.08, paragraph II.A.4.(c). Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

In this case the diesters differ by the inclusion of a single methylene group in the prior art compound. Thus there is a presumed expectation that such compounds possess similar properties.

Claims 60-69 are included because the carbohydrate moieties differ from the carbohydrate moiety of Akelah by the addition of a diol (CHOHCHOH). As discussed above, compounds differing regularly by the successive addition of the same chemical group are generally of sufficiently close structural similarity that there is a presumed

expectation that such compounds possess similar properties. Addition of two CHOH groups would have been presumed to yield a compound with similar properties. Furthermore, absent evidence of unexpected results, stereoisomers are considered to be prima facie obvious over each other (MPEP 2144.09 (II).

Thus the invention as a whole was prima facie obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Tracy Vivlemore, can be reached at (571) 272-2914. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Richard Schnizer/
Primary Examiner, Art Unit 1635